

Remarks

Claims 1-12 and 16-33 were previously pending in the subject application. By this Amendment, the applicants have amended claims 23 and 28 and have cancelled claims 24 and 29-31. Further, the applicants have cancelled claims 1-12, 16-22 and 32 as being drawn to non-elected subject matter. Support for the amendments to the claims can be found throughout the subject specification including, for example, at page 8, second full paragraph, and page 22 second full paragraph. Accordingly, claims 23, 25-28, and 33 are pending in the subject application.

The amendments presented herein have been made to lend greater clarity to the claimed subject matter and to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicants wish to thank the Examiner for the careful review of the subject specification. Specifically, the applicants have amended the specification to correctly reference trademarks. Paragraph designations have been made relying on the published application as referenced in the Office Action.

Claim 31 has been rejected under 35 USC §112, second paragraph. In order to expedite prosecution, claim 31 has been cancelled herein, thereby rendering moot this ground for rejection.

Claims 23-31 and 33 have been rejected under 35 USC §112, first paragraph as being non-enabled for the full scope of the claims as previously presented. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

The Office Action notes that the claims are enabled for treatment of certain disorders, but questions whether they are enabled for prevention of the disorders. In order to expedite prosecution, the applicants have amended their claims herein to eliminate recitation of "prevention."

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection of claims 23-31 and 32 under 35 USC §112, first, paragraph as being non-enabled.

Claims 23, 25-27, 29-31 and 33 have been rejected under 35 USC §112, first paragraph for lacking written description support. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination.

In making this rejection, the Office Action focuses on claims 23 and 29 and states at page 25:

The generic statements protease inhibitor and pharmaceutically active agents do not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

While the applicants do not agree with this ground for rejection, in order to expedite prosecution, claim 23 has been amended herein to specifically refer to the use of "alpha-1-antitrypsin" and claim 29 has been cancelled.

The test for an adequate written description has been stated in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

It is respectfully submitted that applicants have met this test given the teachings of the specification and the scope of the claims as amended herein. Accordingly, the applicants respectfully request reconsideration and withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph.

Claims 23-31 and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by *Estis et al.* (US Patent No. 4,680,175). The applicants respectfully traverse this ground for rejection because the *Estis et al.* reference does not teach the current applicants' advantageous method.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

The claims, as amended herein, are drawn to an advantageous method of treating ichthyosis by administering alpha-1-antitrypsin. The Estis *et al.* reference does not teach this method.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 23-24, 27-28, 30-31 and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lezdey *et al.* (US Patent No. 6,096,327), as evidenced by Diseases of the Epidermis (https://atlases.muni.cz/atlases/kuze/atl_en/main+nenadory+epidpor.html). The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims now presented for examination because the cited reference does not disclose the applicants' method as currently claimed.

The claims, as amended herein, are drawn to an advantageous method of treating ichthyosis by administering alpha-1-antitrypsin. The Lezdey *et al.* reference does not teach this method.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 23, 24, 27-31 and 33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lezdey *et al.* (US Patent No. 6,096,327), as evidenced by Diseases of the Epidermis (https://atlases.muni.cz/atlases/kuze/atl_en/main+nenadory+epidpor.html) in view of

Lezdey (WO 92/06706). The applicants respectfully traverse this ground of rejection because the cited references, either taken alone or in combination, do not teach or suggest the claimed method.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (2007). Furthermore, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." *Id.*

Nothing in the cited references would have led the skilled artisan to the method as now claimed. The Office Action states at page 2:

A search was conducted on the elected species, ichthyosis, and it appears to be free of prior art.

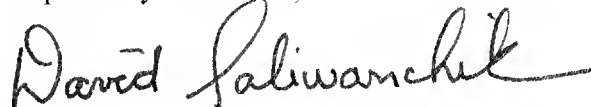
The applicants agree with this analysis and, in order to expedite prosecution, the claims have been amended herein to recite the treatment of ichthyosis with alpha-1-antitrypsin. As noted in the Office Action, this embodiment of the subject invention is free of prior art. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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